

K210931 Libby IAAA v1.0Dec 17, 2021
263 days to decisionK210931 · Product code: **LLZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k210931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 29, 2021
Decision date	Dec 17, 2021
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dyad Medical, Inc.
Location	Boston, MA, US
Contact	Ronny Shalev
510(k) history	2 submissions · 2 cleared · 2021-2022

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